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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,184	01/14/2000	Ruth W. Craig	DART1110-1	8067

7590 09/26/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/483,184	Applicant(s) Craig et al	
Examiner Karen Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 10-21 is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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Response to Amendment

1. Claim 10 has been amended. Claims 1-21 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

3. The rejection of claims 10-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in light of applicants arguments.

Claim Rejections Maintained

4. The rejection of claims 1-9 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility, is maintained for reasons of record.
5. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph is also maintained, as one of skill in the art would not know how to use the claimed products which lack utility.

Applicant argues that the claimed gene regulatory element would not be used as a subject for further research but would be useful as a tool that allows for the identification of agents that can modulate the activity of said regulatory element. Applicant further argues that a screening assay for said agents would have a specific, substantial and credible utility because companies have been formed and provide services based on drug screening platforms. Applicant points out that Idun pharmaceuticals is a company that has developed drug screening platforms based on apoptotic pathways and used the drug screening assays to identify agents that can modulate apoptosis. Applicant further states that Genelab Technologies also screen for drugs that can modulate gene expression. This has been considered but not found persuasive. However, neither

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the specification nor any art of record identifies utilities for the Mcl-1 regulatory gene element, regardless of its putative beneficial uses. Regarding the activities of Idun Pharmaceuticals or Genlab Technologies and the discovery of agents which can modulate the activity of the Mcl-1 regulatory gene element, it is the responsibility of the applicants, not the purchaser, who must disclose the utility of the polynucleotide order to satisfy the requirements of patent law. For these reasons, utility cannot be equated to commercial value. Further, the use of a polynucleotide regulatory element in a screening assay is not a specific use as any gene regulatory element can be used in said screening assay.

The use of the regulatory gene element to discover agents which can modulate the activity of said regulatory element is using the claimed invention for further research, contrary to applicants arguments. Without knowing what specifically is needed to activate or suppress the regulatory element, one of skill in the art would not know how to use said element. The discovery of agents which can activate or suppress, enhance or diminish the activity of said regulatory element is the part of the act of discovery of how to use said regulatory element, and until these agents have been identified and a patentable use for said regulatory element disclosed, the invention is incomplete.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

August 30, 2002

AC
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